REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim Amendments

Claims 1-6, 21-35 stand withdrawn as being drawn to a non-elected invention. Claims 17-19 and 48-50 stand withdrawn as being drawn to non-elected species.

Claims 8, 14, and 37 are requested to be canceled.

Claims 7, 9-13, 15-20, 36, and 38-50 currently are amended. No new matter is added by these amendments. Support for the amendment can be found in the application as filed. Cancellation or amendment of the claims is not intended to be a dedication of the canceled subject matter to public. Applicants reserve the right to file one or more continuation applications on the canceled subject matter. The support for the amendments can be found as follows.

Claims 7, 9-13, 15-20, 36, and 38-50 are amended to add the phrase "heat or irradiation" and support for the amendment can be found in the specification, for example, on pages 47-48, paragraph [00219] of the application as filed.

Claims 7, 17, and 36 are amended to recite the Markush group from which the rheological modifier is selected, and support for the amendment can be found in the specification, for example, on page 21, paragraphs [0098] and [0099], and page 22, paragraph [00101] of the application as filed. Claims 7, 17, and 36 are amended to recite the area between the two curves that characterizes the minimal change of the thixotropic behavior, and support for the amendment can be found in the specification, for example in page 7, paragraph [0025] and original claims 8 and 37. Claim 7 is amended to recite that the composition includes a water insoluble, biocompatible polymer, a biocompatible solvent and optionally a contrast agent, and support for

the amendment may be found in the specification, for example in page 30, paragraph [00133] and in original claim 14.

Claims 9, 15, and 17 are amended to correct their dependency on claim 7. Claim 10 is amended to correct a typographical error. Claim 20 is amended to correct its dependency on currently amended claims 7 and 17. Claim 38 is amended to correct its dependency on claim 36.

Claim 51 is newly added. No new matter is added by this new claim. Support for this claim can be found, for example, on page 22, paragraph [00101] of the application as filed.

Applicants submit that no new matter has been added by this amendment and respectfully request its entry. After amending the claims as set forth above, claims 7, 9-13, 15-16, 20, 36, 38-47, and 51 currently are under consideration.

Election/Restrictions

Applicants would like to make a clarification regarding the Non-Final Office Action stating that "Applicant's election with traverse of Group I... is acknowledged." The election with traverse was of Group II, not Group I. Although the Applicants' Response of February 21, 2007 stated that Applicants elected Group I, a subsequent Communication dated March 1, 2007 noted that "Group I" was a typographical error and that it was Group II that was elected.

The currently amended claims 7, 9-13, 15-16, 20, 36, and 38-47 read on elected species

A. The withdrawn/currently amended claims 48-50 read on non-elected species B and

Applicants request the Office that these claims be rejoined after species A is found allowable.

Claim Rejections under 35 U.S.C. § 112, first paragraph

Claims 7-16 and 36-47 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office alleges that the Applicants claim a hydroxyl containing rheological modifier in an effective amount to impart

shear thinning while the specification only gives written support for a limited number of types of rheological agents that can be used in the invention. *See* page 3 of Office Action.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

In order to expedite prosecution, Applicants have amended the instant claims to define the modifier to be selected from fumed silica, poly(2-hydroxyethylacrylates), copolymers of ethylene and maleic acid, polyvinylalcohol, oxidized poly(alkenes), hydroxypropylcellulose, hydroxypropylmethylcellulose, carboxymethylcellulose, sodium hydroxyethylcellulose, hydroxyethylcellulose, methylcellulose, poly(2-hydroxyethylmethacrylates), poly(saccharides), poly(siloxanes), carrageenan, guar, xanthan gum, locus bean gum, homo- and co-polymers of mannuronic acid and glucuronic acid and particulate rheological modifier. There is support in the specification for the claims as now presented. *See*, e.g., the specification at page 21, paragraphs [0098] and [0099] and page 22, paragraph [00101] of the application as filed. Therefore, the specification describes the claimed invention in sufficient detail such that a person of skill in the art can reasonably conclude that the inventor had possession of the claimed invention.

Withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 7-16 and 36-47 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Office states that the term

"effective amount" and the term "minimal change" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See pages 3-4 of the Office Action.

Applicants traverse the rejection for the following reasons.

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

See MPEP §2173.02.

A. The term "effective amount"

Applicants assert that the term "effective amount" in claims 7 and 36 is not a relative term which renders the claim indefinite. The effective amount of the rheological modifier is related to the amount of the biocompatible polymer as is evident from the disclosure in the specification which is as follows. For example, on page 34, paragraph [00154] and on page 39, paragraph [00181], the specification recites that preferably, the composition will comprise from about 1:1 to about 2:1 weight of biocompatible polymer or prepolymer to the rheological modifier, and even more preferably from about 1.2:1 to about 1.4:1 weight of biocompatible polymer or prepolymer to the rheological modifier. Additionally, for example, on page 35, paragraph [00159], the specification recites that a preferred "composition has a range of biocompatible polymer (weight/volume solvent) to fumed silica (weight/final weight) of from at least about 2.6 to 1 to about 3.6 to 1. More preferably, the ratio is from about 3.0 to 1 to about 3.2 to 1. Even more preferably, the ratio is about 3.1 to 1." The specification goes on to provide examples of such composition on page 35, paragraph [00161] and page 36, paragraph [00163]. Hence, the effective amount of the rheological modifier has been defined in the present

application in terms of its ratio with the biocompatible polymer. Therefore, a person of ordinary skill in the art would be apprised of the scope of the invention in light of the disclosure in the specification.

For the foregoing reasons, withdrawal of this rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

B. The term "minimal change"

The term "minimal change" is also not a relative term which renders the claim indefinite. The "minimal change" is characterized by an area between the two curves measuring shear stress at increasing and decreasing shear rates measured at from 0 to 250 s-1 of no more than about 25,000 Pa/sec (page 7, paragraph [0025] of the application as filed). In order to expedite prosecution, Applicants have amended claims 7 and 36 to further read "... and said area between the two curves is from about area 1,000 to about 20,000 Pa/sec." The amendment to the claim has obviated this rejection.

Withdrawal of this rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claim Rejections under 35 U.S.C. § 102

Applicants would like to summarize the salient features of the invention before discussing the rejections.

The instant application discloses that attempts at heat sterilizing the embolic compositions comprising a rheological modifier have resulted in sterilized compositions having undesirable thixotropic properties and having an adverse effect on the viscosity. See page 5, paragraph [0016] and Figure 1 of instant application as filed. Therefore, it is important that the pseudo-plastic characteristics established for the composition prior to sterilization do not materially change after sterilization and that the viscosity of the sterilized composition remain stable over time. See page 5, paragraph [0014] of the instant application as filed.

The claimed invention is directed to a discovery that sterilization of embolic compositions comprising hydroxyl-containing rheological modifier using heat or irradiation techniques provides sterilized compositions exhibiting minimal change in its thixotropic behavior as compared to the composition prior to sterilization with reduced variability from sterilized product to sterilized product. Therefore, sterilization of the embolic composition is an essential characteristic of the invention. The claims have been amended herein to better define this essential characteristic by adding the phrase "heat or irradiation" sterilized embolic composition.

A. Kaleta et al. (U.S. Pat. No. 5,618,522)

Claims 7-16, 20, and 36-47 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Kaleta *et al.* (U.S. Pat. No. 5,618,522). Applicants respectfully traverse this rejection for the reasons that follow.

To anticipate a claim, a single source must contain all of the elements of the claim. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Kaleta et al. do not contain all the elements of the claim. Kaleta et al. define oil-in-water emulsion compositions useful for topical application to human skin where the compositions contain amongst several other ingredients, thickener such as silica, polymers and solvents. However, Kaleta et al. disclose no teaching of sterilization of the composition and the impact of sterilization on the thixotropic behaviour of the sterilized composition. On the contrary, Kaleta et al. disclose oil in water emulsions that are for topical application (see abstract of Kaleta et al.). Since the compositions of Kaleta et al. are for the topical application, it is inherent that the compositions are not sterilized. Meanwhile, the claimed invention is directed to a heat or irradiation sterilized composition wherein the sterilized composition exhibits a minimal change in its thixotropic behavior as compared to the composition prior to sterilization. The sterilization of the composition is an essential characteristic of the claimed invention which is absent in Kaleta et al.

The Office states that there was no weight given to preamble since where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See page 5 of the Office Action. Applicants traverse for the reasons that follow.

If the preamble of a claim discloses a fundamental characteristic, it is considered a claim element requiring construction. *Poly-America L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1309-10 (Fed. Cir. 2004).

Applicants submit that the preamble reciting, a "heat or irradiation" sterilized embolizing composition of the claimed invention, is directed to a fundamental characteristic of the invention and thus must be considered a claim element. The sterilization of embolic compositions comprising hydroxyl-containing rheological modifier using irradiation techniques provides sterilized compositions exhibiting minimal change in its thixotropic behavior as compared to the composition prior to sterilization with reduced variability from sterilized product to sterilized product. See page 6, paragraph [0022] of the application as filed. Thus, the cited art must contain this claim element in order to anticipate the instant claims. Kaleta et al. discloses no teaching of sterilization of the composition and the impact of sterilization on the thixotropic behaviour of the sterilized composition.

The Office alleges that the composition disclosed by the instant claims is not patentably distinct from the compositions disclosed by Kaleta et al. and hence will have the same shelf life characteristics, such as viscosity change. Applicants respectfully disagree with this assertion.

"In relying upon the theory of inherency, the Office must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPO2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)...

There is no teaching in Kaleta et al. that shows that the compositions have prolonged shelf-life with limited changes in viscosity. As such, the instant application discloses that the extended shelf-life experiments demonstrate that heat sterilized compositions comprising hydroxyl-containing rheological modifiers are unstable over time with significant viscosity changes occurring. See page 6, paragraph [0020] of the instant application as filed. Therefore, it is not inherent that the compositions disclosed in Kaleta et al. will have the same shelf life as the composition of the claimed invention.

Kaleta et al. do not disclose compositions that are sterilized, nor is it inherent that the compositions disclosed by Kaleta et al. will be sterile and will have prolonged shelf life. Thus, Kaleta et al. do not disclose all of the claim elements of the instant claims.

For all of these reasons, Applicants request that this rejection under 35 U.S.C. §102(b) be withdrawn.

B. Unger et al. (U.S. Pat. No. 6,139,819)

Claims 7-16, 20, and 36-47 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Unger *et al.* (U.S. Pat. No. 6,139,819). In light of cancellation of the claims, Applicants apply this rejection to the currently pending claims 7, 9-16, 20, 36, and 38-47. Applicants respectfully traverse this rejection for the reasons that follow.

To anticipate a claim, a single source must contain all of the elements of the claim.

Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Unger et al. do not contain all the elements of the claim. Unger et al. disclose compositions that comprise a lipid, a protein, a polymer, and/or surfactant, and a gas in combination with a targeting ligand. The Office alleges that the addition of a viscosity modifier such as silicon dioxide or methyl cellulose meets the limitation of a rheological modifier. However, Unger et al. do not disclose whether the amount of viscosity modifier is in an effective amount to impart shear thinning, pseudo-plastic properties to the compositions, as in the claimed

invention. Unger et al. make no mention of sterilization of the composition and the impact of sterilization on the thixotropic behaviour of the sterilized composition. In contrast, the claimed invention is directed to a heat or irradiation sterilized composition wherein the sterilized composition exhibits a minimal change in its thixotropic behavior as compared to the composition prior to sterilization. The sterilization of the composition is an essential characteristic of the claimed invention which is absent in Unger et al.

The Office applies the same remarks as above in Kaleta et al. to Unger et al. regarding the preamble use, the shelf life and the viscosity of a composition in the absence of rheological agent. For the same reasons as provide above for Kaleta et al., Applicants respectfully submit that Unger et al. also make no mention of sterilization of the composition and the impact of sterilization on the thixotropic behaviour of the sterilized composition. There is also no teaching in Unger et al. that shows that the compositions have prolonged shelf life with limited changes in viscosity. The extended shelf-life experiments in the instant application demonstrate that heat sterilized compositions comprising hydroxyl-containing rheological modifiers are unstable over time with significant viscosity changes occurring. See page 6, paragraph [0020] of the instant application as filed. Therefore, it is not inherent that the compositions disclosed in Unger et al. will have the same shelf life as the composition of the claimed invention.

Unger et al. do not disclose compositions that are sterilized, nor is it inherent that the compositions disclosed by Unger et al. will be sterile and will have prolonged shelf life. Thus, Unger et al. do not disclose all of the claim elements of the instant claims.

For all of these reasons, Applicants request that this rejection under 35 U.S.C. §102(b) be withdrawn.

C. Greff et al. (U.S. Pat. No. 5,580,568)

Claims 7-13 and 36-44 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Greff *et al.* (U.S. Pat. No. 5,580,568). In light of cancellation of the claims, Applicants apply this rejection to the currently pending claims 7, 9-13, 36, and 38-44.

To anticipate a claim, a single source must contain all of the elements of the claim.

Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Regarding claims 7 and 9-13, Applicants submit that the rejection has been obviated by inclusion of the recitation of a non-rejected claim 14 into claim 7. The amended claims 9-13 are dependent on the amended claim 7 and therefore incorporate all the claim limitations of claim 7. Regarding the rejection of claims 36-44, Applicants respectfully traverse for the reasons that follow.

Greff et al. do not contain all the claim limitations. Greff et al. disclose compositions comprising a cellulose diacetate polymer, a biocompatible solvent and a water insoluble contrasting agent. Cellulose diacetate polymer is the embolizing agent in the composition. See col. 2, lines 66-67 of Greff et al. Greff et al. do not disclose a rheological modifier as in the claimed invention. Furthermore, Greff et al. do not disclose thixotropic behavior of the composition as in the instantly claimed invention. Thus, Greff et al. do not contain all the limitations of the claimed invention.

For all of these reasons, Applicants request that this rejection under 35 U.S.C. §102(b) be withdrawn.

D. Porter et al. (WO 2004/035022)

Claims 7-16, 20, and 36-47 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Porter et al. (WO 2004/035022). In light of cancellation of the claims, Applicants

apply this rejection to the currently pending claims 7, 9-16, 20, 36, and 38-47. Applicants respectfully traverse this rejection for the reasons that follow.

To anticipate a claim, a single source must contain all of the elements of the claim. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Regarding pending claims 7, 9-16, and 20, Applicants contend that the compositions disclosed by Porter et al. do not disclose all the claim limitations of the instant claims. The instant claims 7, 9-16, and 20 as amended disclose a composition comprising a rheological modifier, a biocompatible polymer, a biocompatible solvent, and optionally a contrast agent. Porter et al. disclose compositions comprising a pre-polymer which is a monomer and not a biocompatible polymer as in instant claims. This is evident from the examples of the pre-polymers given by Porter et al. on page 7, paragraph [0032] which include for example, acrylates, methacrylates, acrylamides etc. Thus, the compositions disclosed by Porter et al. fail to contain all of the elements disclosed by the instant claims 7, 9-16, and 20 as amended.

Further, Porter et al. do not disclose a sterilized composition wherein there is a minimal change in its thixotropic behavior as compared to the composition prior to sterilization. Porter et al. also do not disclose a sterilized composition exhibiting a prolonged shelf life with limited changes in viscosity, nor is a prolonged shelf life with limited changes in viscosity inherent to all such compositions as described earlier. Because Porter et al. do not disclose sterilized compositions that display minimal changes in thixotropic behavior, the compositions disclosed by Porter et al. do not meet the limitations disclosed by the instant claims.

For all of these reasons, Applicants request that this rejection under 35 U.S.C. §102(e) be withdrawn.

E. Porter (US 2003/0039696)

Claims 7-16 and 20 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Porter (US 2003/0039696). In light of cancellation of the claims, Applicants apply this

rejection to the currently pending claims 7, 9-16, and 20. Applicants respectfully traverse for the reasons that follow

To anticipate a claim, a single source must contain all of the elements of the claim. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Applicants contend that the compositions disclosed by Porter does not contain all of the elements of the instant claims. Porter recites compositions comprising a matrix-forming monomer such as alkyl cyanoacrylate (see for example abstract of Porter and page 3, paragraph [0038]). Therefore, Porter describes compositions that contain monomers and not biocompatible polymers as in instant amended claims. Thus, the compositions disclosed by Porter do not contain all of the elements disclosed by the instant amended claims 7, 9-16, and 20. Withdrawal of this rejection is respectfully requested.

F. Greff (US 2003/0228273)

Claims 7-16 and 20 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Greff (US 2003/0228273). In light of cancellation of the claims, Applicants apply this rejection to the currently pending claims 7, 9-16, and 20. Applicants respectfully traverse this rejection for the reasons that follow.

To anticipate a claim, a single source must contain all of the elements of the claim. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Applicants contend that the compositions disclosed by Greff do not contain all of the elements of the instant claims. Greff recites compositions comprising a biocompatible prepolymer (see for example, page 2, paragraph [0029] and paragraph [0032] of Greff). Therefore, Greff describes compositions that contain monomers which polymerize in situ to form a polymer and do not contain biocompatible polymers as in instant amended claims. Thus, the compositions disclosed by Greff do not contain all of the elements disclosed by the instant amended claims 7, 9-16, and 20. Withdrawal of this rejection is respectfully requested.

Claim rejection under obviousness-type double patenting

A. Claims 7-13, 36-39, and 41-44 stand rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1 and 7 of U.S. Patent No. 5,580,568 (hereinafter "the '568 Patent").

The Office alleges that the instant claims and the claims in the '568 Patent are not patentably distinct from each other because both claim embolizing compositions comprising a hydroxyl-containing rheological modifier. See page 9 of the Office Action. Applicants respectfully traverse this rejection for the reasons that follow.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The '568 Patent discloses compositions comprising a cellulose diacetate polymer, a biocompatible solvent and a water insoluble contrasting agent. Cellulose diacetate polymer is the embolizing agent in the composition. See col. 2, lines 66-67 the '568 Patent. The '568 Patent does not disclose a rheological modifier nor is cellulose diacetate polymer a rheological modifier. In contrast, the instant amended claims are directed to a composition that comprises a rheological modifier in the composition. Therefore, the compositions of the '568 Patent are patentably distinct from the compositions of the claimed invention. Further, there is no suggestion or motivation in the '568 Patent to a person of skill in the art to add a rheological modifier to the composition of the '568 Patent to come up with the claimed invention. Furthermore, in the absence of a suggestion or motivation in the '568 Patent, there is no reasonable expectation of success to a person of skill in the art to add a rheological modifier to the composition.

For the reasons provided as above, Applicants request that this nonstatutory obviousnesstype double patenting rejection be withdrawn. B. Claims 7-16, 20, 36-39, and 41-44 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over Application No. 10/789.436 (hereinafter "the '436 Application").

The Office asserts that the instant claims and the claims of the '436 Application are not patentably distinct from each other because both claim compositions comprise hydroxyl containing rheological agent, fumed silica. See page 9-10 of the Office Action. Applicants respectfully traverse this rejection for the reasons that follow.

The compositions of the claimed invention are patentably distinct from the compositions of the '436 Application. The '436 Application does not disclose a sterilized composition that exhibits a minimal change in thixotropic behavior as compared to the composition prior to sterilization. At best the '436 Application discloses a sufficient amount of fumed silica to impart a shear thinning index to the composition of at least about 4. See page 7, paragraph [00019] of the '436 Application. There is, however, no teaching of the sterilization of the composition or a sterilized composition that exhibits a minimal change in thixotropic behavior as compared to the composition prior to sterilization. In contrast, the instant amended claims are directed to a sterilized composition that exhibits minimal change in thixotropic behavior as compared to the composition prior to sterilization wherein such minimal change is characterized as defined in the claimed invention. Such minimal change in thixotropic behavior results in a constant delivery profile of the composition wherein the composition may be reproducibly delivered after repeated increases and decreases in shear stress. See pages 4-5, paragraph [0013] and pages 6-7, paragraph [0022]. Therefore, the compositions of the '436 Application are patentably distinct from the compositions of the claimed invention. Further, there is no suggestion or motivation in the '436 Application to a person of skill in the art to prepare a sterilized composition that exhibits a minimal change in thixotropic behavior as compared to the composition prior to sterilization.

For the reasons provided as above, Applicants request that this nonstatutory obviousnesstype double patenting rejection be withdrawn.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Office is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date _____09 | 19 | 07

FOLEY & LARDNER LLP Customer Number: 38706 Telephone: (650) 251-1139

Facsimile: (650) 856-3710

Vandana Bansal, Ph.D.

Vandana Bansal, Ph.D.
Patent Agent
Registration No. 54,979